Citation:

Fung TT, Hu FB, Holmes MD, Rosner BA, Hunter DJ, Colditz GA, Willett WC. Dietary patterns and the risk of postmenopausal breast cancer. Int J Cancer. 2005;116:116-121.

PubMed ID: <u>15756679</u>

Study Design:

Prospective Cohort Study

Class:

B - <u>Click here</u> for explanation of classification scheme.

Research Design and Implementation Rating:



POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

The purpose of this study was to identify major dietary patterns in a cohort of women and prospectively examine their associations with postmenopausal breast cancer.

Inclusion Criteria:

Women from the Nurses'Health Sudy who completed the 1984 Food Frequency Questionnaire (FFQ) with fewer than 70 missing items (out of 116 items) and their total energy intake (as calculated from the FFQ) was between 500 and 3,500 kcal/day.

Exclusion Criteria:

Women were excluded from this study if they had a history of cancer at baseline, except nonmelanoma skin cancer or *in situ* breast cancers.

Description of Study Protocol:

Recruitment Female nurses who originally participated in the 1976 Nurses' Health Study (NHS) and who responded to the 1984 FFQ and bienniel NHS questionnaire regarding medical, lifestyle and other health-related information.

Design Prospective Cohort Study

Blinding used (if applicable) NA

Intervention (if applicable) NA

Statistical Analysis

- Dietary patterns were identified with statistical procedure factor analysis (principal components based on 38 predefined food groups.)
- Relative Risks were computed using Cox proportional hazard models and adjusted for known risk factors for breast cancer

Data Collection Summary:

Timing of Measurements biennial questionnaire followup for up to 16 years, from 1984 to 2000 along with case ascertainment (breast cancer during that period).

Dependent Variables

• Postmenopausal breast cancer - was determined by self report (in biennial questionnaire responses), deaths reported by the postal service, family members, or by searching the National Death Index. Permission was obtained to review medical records for confirmation for all self-reported cases.

Independent Variables

• Baseline diet pattern scores (based on 38 predefined food groups) which identified dietary patterns (prudent, which was high in fruits and vegetables, and Western pattern which was high in red meat and processed meats) based on the correlations between these food groups.

Control Variables

Cigarette smoking, body weight (BMI), history of benign breast disease, occurrence of menopause and the use of hormone replacement therapy, parity and age at first birth, and physical activites (METs).

Description of Actual Data Sample:

Initial N: 71,058 female

Attrition (final N): N not stated, however, authors reported follow-up for the entire Nurses Study was complete for greater than 95% of the potential person-time up to the year 2000.

Age: 30-55 years of age in 1976

Ethnicity: U.S.

Other relevant demographics:

Anthropometrics (e.g., were groups same or different on important measures)

Location: U.S.

Summary of Results:

Key Findings:

- After adjusting for potential confounders, neither the 1984 prudent pattern nor the cumulative average prudent pattern was associated with overall breast cancer risk.
- For the Western diet pattern, no overall association was observed except among smokers. The multivariate relative risk was 1.44 (95% CI=1.02-2.03; p value for trend = 0.03) comparing top to bottom quintile of Western pattern score in 1984 (p-value for interaction between smoking and Western pattern = 0.20).
- Women with a high 1984 prudent pattern had a lower risk of negative Estogen Receptor (ER -) breast cancer than women with a low prudent pattern. The RR was 0.62 (95% CI = 0.45-0.88; p-value for trend = 0.006) when comparing top to bottom quintile of 1984 prudent pattern score. However, there was no significant association for either the 1984 or cumulative average Western pattern when stratified by estrogen receptor status.
- In associations between intake of the major contributors of the 2 dietary patterns at baseline and risk of ER⁻ breast cancer, inverse associations were observed with vegetables and fruits. Each additional serving of vegetables was associated with 6% lower risk (95% CI = 0.88 -0.99; p= 0.03) and each additional serving of fruits was associated with 12% lower risk (95% CI = 0.80 0.97; p=0.009.)

Other Findings

Author Conclusion:

The authors found no overall association between 2 major dietary patterns (Prudent-high in fruits and vegetables, and Western-high in red and processed meats) and the risk of postmenopausal breast cancer. However, for the subset of negative Estrogen Receptor breast cancers, a significantly lower risk was observed with the prudent pattern and with higher intakes of fruits and vegetables. A significantly higher risk was found between the Western pattern and breast cancer risk only among smokers.

Reviewer Comments:

The author acknowledged that the dietary patterns seen in this cohort represent current eating patterns, and that the prudent pattern may not necessarily represent the optimal diet for breast cancer prevention. Additionally, the impact of diet on breast cancer risk may be specific to a particular period in life which was not captured in this study.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)



	2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
	3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
	4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes
Vali	dity Questions		
1.	Was the research question clearly stated?		Yes
	1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
	1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
	1.3.	Were the target population and setting specified?	Yes
2.	Was the sele	ection of study subjects/patients free from bias?	Yes
	2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
	2.2.	Were criteria applied equally to all study groups?	Yes
	2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
	2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	Were study	groups comparable?	Yes
	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
	3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
	3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes

	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
	3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method	of handling withdrawals described?	???
	4.1.	Were follow-up methods described and the same for all groups?	Yes
	4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	???
	4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	???
	4.4.	Were reasons for withdrawals similar across groups?	???
	4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blindin	g used to prevent introduction of bias?	Yes
	5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
	5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
	5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
	5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
	5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.		ention/therapeutic regimens/exposure factor or procedure and ison(s) described in detail? Were interveningfactors described?	Yes
	6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
	6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
	6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
	6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	No

	6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
	6.6.	Were extra or unplanned treatments described?	N/A
	6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
	6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcor	nes clearly defined and the measurements valid and reliable?	Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the stat outcome ind	istical analysis appropriate for the study design and type of icators?	Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	No
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	Are conclusi consideratio	ions supported by results with biases and limitations taken into n?	Yes
	9.1.	Is there a discussion of findings?	Yes

	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes

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